

**AUG 25 2000**

*K000358*

## **510(k) SUMMARY**

Submitter's name: Warepalmy Enterprises LLC (USA)  
1725 NE Orenco Station Parkway  
Hillsboro, OR 97124  
(503) 693-6516

Date summary prepared: February 1, 2000

**Device name:**

Proprietary name: C.T.M. Mobility Scooters HS-666, HS-730, HS-570  
Common or usual name: Electric scooter.  
Classification name: Motorized three-wheeled vehicle, Class II, 890.3800.

**Legally marketed device for substantial equivalence comparison:**

C.T.M. Mobility Scooter HS-666 submitted by Warepalmy Enterprises LLC (USA) and cleared for marketing under 510(k) #K983663.

**Description of the device:**

The C.T.M. Mobility Scooters models HS-666, HS-570, and HS-730 are indoor/outdoor three-wheeled scooters that are battery operated. They are modifications of the original scooter HS-666. They vary in parameters such as exterior dimensions and accessories. All three scooters contain software imbedded in the scooter controller.

**Intended use of device:**

The C.T.M. Mobility Scooters HS-666, HS-570, and HS-730 are all indoor/outdoor scooters that provide transportation for a disabled or elderly person.

**Technological characteristics:**

This submission describes two general types of changes to the original C.T.M. Mobility Scooter HS-666. The first is a description of the software component that was not described in the original submission. The second is the addition of two models that are slight variations of the HS-666.

**Performance testing:**

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 25 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Warepalmy Enterprise LLC (USA)  
c/o Mr. Robert S. McQuate  
R.S. McQuate & Associates, Inc.  
3636 East Columbine Drive  
Phoenix, Arizona 85032-7372

Re: K000354

Trade Name: C.T.M. Mobility Scooters HS-666, HS-730, HS-570  
Regulatory Class: II  
Product Code: INI  
Dated: August 4, 2000  
Received: August 8, 2000

Dear Mr. McQuate:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 – Mr. Robert S. McQuate

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Neil R. Ogden".

Celia M. Witten, Ph.D., M.D. *for*

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): K000354

Device name: C.T.M. Mobility Scooters HS-666, HS-730, and HS-570

Indications for Use:

The C.T.M. Mobility Scooters are indoor/outdoor scooters that provide transportation for a disabled or elderly person.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NPO for cmw

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K000354

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use   X